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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2004D-0251

Dear Sir/Madame:

This letter represents the comments of the National Electrical Manufacturers Association (NEMA) on the *Draft Guidance for Industry, FDA Staff, and FDA-Accredited Third-Parties: Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002.* Docket No.2004D-0251. We appreciate the opportunity to share our views with you.

NEMA is the largest U.S. trade association representing America's electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents over 90% of the market for x-ray imaging, CT, radiation therapy, diagnostic ultrasound, nuclear medicine imaging, magnetic resonance and medical imaging informatics equipment.

On June 3, 2004, FDA announced the availability of the above-entitled draft guidance. Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorized FDA-accredited third parties (accredited persons or APs) to conduct inspections of Class II and Class III device manufacturers which met specific eligibility criteria as defined by the statute. The draft guidance sets forth the establishment eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an AP, instead of FDA, conduct an inspection of their establishment, under the (Accredited Persons) AP program.

We recognize FDA's efforts to be flexible in the establishment and operation of this program. However, we are deeply concerned that specific elements of this draft guidance could render the entire Third Party Inspections program so burdensome to companies that it would discourage their participation in it. This is critical to the success of the program since participation in the program is voluntary. As a result, we are hopeful that our concerns can be addressed so that the Third Party Inspections program can become a success.

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First, with regard to the draft guidance, we would like to commend FDA for their recognition of the importance of allowing manufacturers greater control over the timing of their inspections. We agree that greater efficiencies in conducting inspections may be realized in those cases in which APs accredited by the FDA are already recognized by other countries, as persons authorized to conduct inspections of device establishments. In these cases, AP inspections could be concurrently conducted, as the AP would have met the requirements of more than one regulatory authority. This would then reduce the need for multiple inspections of the same establishment.

We appreciate that FDA has adopted a flexible approach in the draft guidance in order to meet eligibility requirements for the third party inspection program, specifically,

"First, a country may already accept FDA's Certificates to Foreign Governments or Certificates of Exportability... These certificates specifically include FDA's acknowledgement of compliance with GMP requirements"

In the draft guidance, FDA also permits manufacturers to exercise under certain conditions an additional option of securing a letter from an appropriate foreign government office. A third option is the preparation and submission to FDA of a signed statement that the law of the foreign country in which the manufacturer intends to market his device recognizes inspections of the FDA or AP for evaluating manufacturing operations and compliance.

However, while the agency has shown flexibility with respect to the matters cited above, we have serious concerns whether the language of the draft guidance would permit "cumulative" inspections over a two-year period. First, there is ambiguity in the language of the draft guidance whether two or more "cumulative" inspections during a two-year period would be permitted under the AP program. If this practice were not permitted, this would be a serious deficiency and we are doubtful manufacturers would volunteer to participate in this program. Moreover, even if "cumulative" inspections were permitted, if the application (or re-application) process were burdensome, time consuming or introduced unnecessary uncertainty into a company's inspectional regime, this would strongly discourage participation in the program.

It is important to note that many manufacturers, in order to comply with international and other national regulatory standards, will be inspected once or even twice in a single year. Under this kind of approach, many manufacturers choose to undergo cumulative "partial" inspections to comply with international quality systems auditing requirements. This is in contrast with the FDA legislative standard of a single inspection every two years. One of the requirements for manufacturers interested in taking part in this program is reconciling the timing of the FDA's statutory requirement to perform inspections on a once every two years basis with the multiple time a year audit approach used in other international registration programs—without unnecessary burden to the manufacturer. In this regard, it is important to note that the

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Medical Devices Technical Corrections Act (Pub. L. 108-214) mad a significant change in paragraph 6(A) (ii) of the original MDUFMA language.

Congress clarified its intent with this change by declaring in the conference report on the Medical Devices Technical Corrections Act (H. Rpt. 108-433), "Section 2 ensures that facilities can work with third party inspectors to allow them to complete a full 510(h) inspection over the course of a two year period." Further, we believe that the Act, by changing the word from "inspection" to "inspections" and adding the phrase, "during a two year period" demonstrates that Congress intended for the AP program to accommodate the timing and nature of other existing international regulatory processes while focusing, for the FDA requirements, on the unique "content" requirements of an FDA inspection.

Under this legislative change made by Congress in the Act, this section of the law now reads,

"(ii) With respect to inspections to be conducted by an accredited person during a 2-year period-

I. the owner or operator of the establishment submits to the Secretary a notice requesting clearance to use an accredited person to conduct the inspection, and the Secretary provides such clearance; and

II. such notice identifies the accredited person whom the establishment has selected to conduct the inspection, and the Secretary agrees to the selected accredited person."

We are concerned that the language in the draft guidance is sufficiently ambiguous to cast into doubt whether such "cumulative" or "partial" inspections over a two-year period would be permitted.

We are deeply concerned that even if they are to be permitted, the apparent requirement that a company must re-apply repeatedly for each portion of an inspection during a two-year period for the next element of their cumulative inspection that this would be so time consuming and burdensome as to discourage participation in the program.

For example, under Section C. Inspection History, with respect to how a firm's inspection history affects its participation in the AP Program, it states,

"You may qualify for the AP program if your most recent device inspection, performed either by FDA or by an AP under the AP Program was classified as either NAI (no action indicated) or VAI (voluntary action indicated)."

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This would appear to suggest that the applicant must re-apply after each inspection even if it was a "partial" inspection that was part of a cumulative process that would address the necessary FDA requirements by the end of a two-year process.

Further, concerning the information which should be submitted regarding the firm's inspectional history, it is stated,

"Once independent AP inspections are underway, you may instead identify the date your firm was inspected by an AP if that is the most recent inspection of your firm that FDA classified."

Both of these examples could be interpreted as discouraging "cumulative" or multiple "partial" inspections during a two-year period because of the burdensome potential of repeated re-applications. In addition, there clearly does not appear to be any "expedited" application process laid out for companies that opt to have more frequent inspections during a two-year period.

NEMA is concerned that a manufacturer who wished to have more frequent "cumulative" inspections would need to re-apply to FDA to request an inspection by an AP after each individual inspection. Re-application after each inspection would constitute a time consuming and unnecessary burden for these manufacturers. This would frustrate the intent of the guidance, which is to facilitate flexibility and efficiency in device inspections.

This is a critical matter that must be addressed if the program is to be a success. There are no medical device companies that we are currently aware of that would be willing to participate in a inspections program that requires re-application for each "partial" inspection during a two-year period that would cumulatively amount to an FDA inspection during the same two-year period.

While we recognize that the Agency legitimately needs to be able to promptly address any problems that arise during an inspection to FDA requirements (whether a single, full FDA inspection or part of a cumulative inspection to be completed over a two-year period), we believe for this program to work, companies who are using a "cumulative" inspections process and in cases where no major violations have been found must be able to go forward with this process without reapplying to the FDA for each part of their cumulative inspections process until the beginning of the next two-year period.

On another matter, we note that there is no explicit statement in the draft guidance that an AP inspection satisfies the requirement for a biennial FDA (510(h)) inspection. On page 2 at the bottom of the "Discussion" section, it reads,

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"Under the act, domestic manufacturers of Class II or Class III medical devices must be inspected for compliance with Good Manufacturing Practices (GMP) requirements and other applicable requirements at least once every two years (21 USC 360(h). One major benefit of the AP Program is that it enables eligible manufacturers to schedule such inspections at the same time in which they will be inspected by other regulatory authorities or organization, thereby reducing the number of disruptions to the establishment's normal operations."

This paragraph does not explicitly state that an inspection by an AP qualifies a facility to have met the statutory requirement that it be inspected to FDA standards at least once every two years. There should be an explicit statement in the guidance that an AP inspection (resulting in NAI or VAI) satisfies the statutory biennial inspection requirement for a company. An explicit statement would allow a manufacturer to demonstrate confidence to the public in its manufacturing processes such that it voluntarily complies with the FDA inspectional requirements.

Under Section A., Device Eligibility Requirements, it states,

"The device you market in the United States and the device you market or intend to market in one or more foreign countries do not have to be the same device, as long as they are manufactured in the same establishment."

This requirement is not found in the MDUFMA-related language authorizing and governing the Third Party Inspections Program.

Finally, a complete reference to the third party inspections authorizing language should be included in the guidance. The guidance references Section 201 of the MDUFMA as the basis for the program. Since the Act made several important adjustments in the original language, it should be referenced in the guidance as well.

In conclusion, NEMA believes that revising the draft guidance to allow for multiple inspections will make this document consistent with the intent of MDUFMA to facilitate efficiency and flexibility in the inspection process and move toward global harmonization of inspection requirements.

We again appreciate the opportunity to share our views with you. If you have any questions, please feel free to contact me. I can be reached at (703) 841 – 3248, or at ric _ eaton@nema.org.

Sincerely,

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Industry Manager

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